

Texas Intellectual Property Law Journal
Spring 2011

Article

**THE FEDERAL CIRCUIT’S INTERPRETATION AND APPLICATION OF THE MEDIMMUNE STANDARD
FOR DECLARATORY JUDGMENT JURISDICTION**

Kelsey I. Nix^{at} Laurie Stempler^{dl}

Copyright (c) 2011 Intellectual Property Law Section of the State Bar of Texas; Kelsey I. Nix; Laurie Stempler

I.	Introduction	332
II.	Declaratory Judgment Jurisdiction: Past and Present	332
	A. Declaratory Judgment Act	332
	B. MedImmune, Inc. v. Genentech, Inc.	335
III.	Requirements For Establishing Declaratory Judgment Jurisdiction Post- MedImmune	336
	A. Substantial Controversy	337
	1. Offers and Demands to License a Patent	337
	2. Correspondence Between the Patentee and Accused Infringer	340
	3. Industry Litigation and Public Statements	343
	4. Covenants Not to Sue	345
	5. ANDA Submissions	347
	B. Immediacy and Concrete Steps	352
IV.	Constitutional Minimum: Standing, Ripeness, and Mootness	354
	A. Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.	354
	B. Prasco, LLC v. Medicis Pharm. Corp.	356
V.	Discretionary Dismissal	358
VI.	Implications	359

***332 I. Introduction**

The Supreme Court recast the requirements for declaratory judgment jurisdiction for patent cases in *MedImmune, Inc. v.*

Genentech, Inc. in 2007, replacing the Federal Circuit's "reasonable apprehension" test with the "substantial controversy" test.¹ The Federal Circuit has since issued twenty-one decisions substantively applying the MedImmune test, twelve of which found an actual case or controversy.

Many post-MedImmune cases have involved potential licensees who declined to pay royalties to patent owners or generic pharmaceutical companies who filed Abbreviated New Drug Applications (ANDAs) and sought declarations of patent invalidity and non-infringement.² The Federal Circuit found jurisdiction in four of its five cases involving licensing disputes and in three of its six ANDA cases.

This article reviews Federal Circuit patent cases decided post-MedImmune. Part II discusses the enactment of the Declaratory Judgment Act, along with the evolving standards that courts have applied to determine whether jurisdiction for a declaratory judgment exists. Part II also briefly introduces the impact of declaratory judgment on patent cases. Part III discusses the Federal Circuit's significant post-MedImmune decisions. Part IV examines the Federal Circuit's parallel analysis of declaratory judgment jurisdiction under the Article III constitutional requirements of standing, ripeness, and mootness. Part V briefly discusses district courts' ability to exercise discretion in determining whether declaratory judgment jurisdiction exists. Finally, Part VI considers some of the long-term implications of MedImmune.

II. Declaratory Judgment Jurisdiction: Past and Present

A. Declaratory Judgment Act

Before enactment of the Declaratory Judgment Act (DJA) in 1934, a party alleging patent infringement could obtain a remedy at law and bring a separate equity action.³ However, the greatest relief that an accused infringer could hope to obtain *333 was dismissal of the action.⁴ Courts did not issue declarations of invalidity or non-infringement, so accused infringers had to accept the potential harm to their reputations that an infringement accusation inflicted.⁵

The enactment of the DJA was preceded by several state statutes that provided declaratory judgment relief. The pattern began with New Jersey enacting a statute allowing for a declaratory judgment action in its state courts in 1915.⁶ New Jersey was the first state to have such a statute, but the Commissioners of Uniform State Laws approved the Uniform Declaratory Judgment Act (UDJA) soon afterwards in 1922.⁷ The UDJA's primary provisions give courts the "power to declare rights, status, and other legal relations," such that the court's declaration "shall have the force and effect of a final judgment or decree."⁸ The UDJA grants courts discretion to refuse to issue a declaratory judgment when it would not resolve a controversy.⁹ It also provides parties with an opportunity to seek review of the judgments.¹⁰ Since its enactment, forty states have adopted the UDJA, and most remaining states have a statute providing declaratory judgment relief.¹¹

The DJA, 28 U.S.C. § 2201, was enacted in 1934, shortly after the Supreme Court ruled that the Uniform Declaratory Judgment Act was constitutional.¹² The DJA allows parties to adjudicate disputes before suffering significant damages.¹³ Under the DJA, "any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration" provided that an "actual controversy" exists.¹⁴

In the context of patent lawsuits, a declaratory judgment action enables a party who would potentially be an accused infringer--and therefore a defendant--to initiate a lawsuit against the patent owner.¹⁵ The DJA enables courts to declare patents *334 invalid or not infringed, thus avoiding litigation that a declaratory judgment plaintiff might have faced after launching its product.¹⁶ Initially, a plaintiff in a patent case was required to show actual or potential infringement and actual or potentially infringing conduct.¹⁷ The test was later revised to require "(1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit [the reasonable apprehension test]; and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such an activity."¹⁸ While courts applied this two-part test for several decades, the Federal Circuit's application of the test has arguably varied with the facts of each case.¹⁹ Finally, even if an actual controversy between the parties is found, the district court has discretion to decline to exercise jurisdiction.²⁰

*335 B. MedImmune, Inc. v. Genentech, Inc.

In 2007, the U.S. Supreme Court overruled the reasonable apprehension test in *MedImmune, Inc. v. Genentech, Inc.* as being

too restrictive.²¹ The case centered on MedImmune's potential exposure to liability under a license, which covered Genentech's existing patent and a pending patent application.²² MedImmune paid royalties to Genentech on sales of the licensed products.²³ But when Genentech's pending patent application was granted and Genentech attempted to obtain royalty payments for the newly issued patent, MedImmune stated that it did not infringe the patent and that the patent was invalid and unenforceable.²⁴

Rather than risk liability for infringing the newly issued patent, MedImmune continued to pay royalties under the agreement but filed a declaratory judgment action to clarify its rights.²⁵ The district court dismissed the case for lack of subject matter jurisdiction.²⁶ The Federal Circuit affirmed the dismissal, applying its reasonable apprehension of suit test.²⁷ That test requires a declaratory judgment plaintiff to (1) have a reasonable apprehension that it would face an infringement suit, and (2) conduct activities that would constitute infringement.²⁸ The court reasoned that as long as MedImmune continued to fulfill its obligations under the licensing agreement, it could not reasonably fear being sued.²⁹

The Supreme Court reversed the decision. Noting that the case would have been a clear "case or controversy" under Article III of the U.S. Constitution if MedImmune had refused to pay royalties, the Court cited several cases involving the government where declaratory judgment jurisdiction existed because "the threat-eliminating behavior was effectively coerced."³⁰ The Court stated that a potential infringer should not have to choose between paying royalties or facing an infringement suit, emphasizing that the "involuntary or coercive nature of the exaction [of payment]" constituted an Article III case or controversy.³¹

*336 The Court clarified that Article III requires "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."³² Nevertheless, proving a reasonable apprehension of suit remains a viable way to satisfy the more general MedImmune test.³³ The Court analogized the facts in MedImmune to those in *Altwater v. Freeman*,³⁴ in which the Court found jurisdiction where patent licensees continued to pay royalties for fear of facing treble damages in an infringement suit.³⁵ The Court emphasized that *Altwater* did not focus on the source of the coercion to pay royalties; the threat could easily originate with a private party rather than the government.³⁶ The Court disagreed with Genentech's argument that any controversy between the parties was eliminated when MedImmune promised not to challenge its patents, distinguishing MedImmune's promise to pay royalties on valid patents from a promise to not challenge patent validity.³⁷ The Court also rejected Genentech's argument that MedImmune repudiated the license agreement while nevertheless benefitting from it, finding that MedImmune, rather than repudiating the contract, asserted that the contract did not prohibit MedImmune from challenging the patents.³⁸

III. Requirements For Establishing Declaratory Judgment Jurisdiction Post-MedImmune

The post-MedImmune cases in which the Federal Circuit has addressed declaratory judgment jurisdiction share common fact patterns. Situations that have raised the question of whether a substantial controversy exists include a patent owner's act of seeking a license for its patent,³⁹ a patent owner's attempts to discuss its patents with potential infringers,⁴⁰ a patent owner's pattern of enforcing its patents against others in the industry,⁴¹ a patent owner's grant of a covenant not to sue,⁴² and a potential infringer filing an ANDA.⁴³ In addition to a substantial controversy of sufficient immediacy or reality, declaratory judgment jurisdiction requires *337 either present activity that may constitute infringement or concrete steps taken with the intent to conduct such activity.⁴⁴

A. Substantial Controversy

1. Offers and Demands to License a Patent

Post-MedImmune decisions involving licensing negotiations indicate that disagreement over the necessity to pay royalties can suffice to establish jurisdiction, especially when the licensee continues its activity without paying royalties.⁴⁵

In *SanDisk Corp. v. STMicroelectronics*, the first post-MedImmune decision by the Federal Circuit, a manufacturer whose products were expressly accused of infringement during licensing negotiations filed a declaratory judgment action.⁴⁶ STMicroelectronics (ST) initiated licensing discussions regarding fourteen patents directed to flash memory storage products.⁴⁷ ST presented detailed claim charts to SanDisk that compared ST's patent claims to SanDisk's products.⁴⁸ ST's technical experts repeatedly referred to SanDisk's "infringement" of the patents.⁴⁹ At the end of the meeting, ST gave

SanDisk a 300-page packet of materials, including copies of the fourteen patents, reverse engineering reports for SanDisk products, and infringement diagrams.⁵⁰ After the meeting, ST told SanDisk that “ST ha[d] absolutely no plan whatsoever to sue SanDisk.”⁵¹ Six weeks later, SanDisk filed a complaint, accusing ST of infringing one of its patents and seeking a declaratory judgment of non-infringement and invalidity of the fourteen ST patents.⁵²

The Federal Circuit found jurisdiction under *MedImmune*. The court held that “where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise.”⁵³ The specific and detailed infringement allegations created substantial ***338** controversy to establish declaratory judgment jurisdiction.⁵⁴ In light of ST’s “studied and considered determination of infringement by SanDisk,” the court dismissed ST’s statement that it would not sue as “the kinds of ‘extra-judicial patent enforcement with scare-the-customer-and-run tactics’ that the Declaratory Judgment Act was intended to obviate.”⁵⁵ As in *MedImmune*, the court observed that a party need not “bet the farm, or [expose itself to] treble damages” before seeking a declaratory judgment.⁵⁶

Unlike *SanDisk*, another 2007 decision, *Adenta GmbH v. OrthoArm, Inc.*,⁵⁷ involved repudiation of existing licensing agreements. Nonetheless, the Federal Circuit reached the same conclusion.⁵⁸ In *Adenta*, a license agreement required royalties for two types of orthodontic brackets.⁵⁹ The licensee, *Adenta*, told the patent holder, *American Orthodontics*, that the licensed patent was invalid and *Adenta* would stop paying royalties.⁶⁰ *American* responded that failure to pay royalties would breach the license and that *American* would “pursue its available legal remedies to protect its rights.”⁶¹ *Adenta* stopped paying royalties and sought a declaratory judgment of invalidity.⁶²

The Federal Circuit relied on its reasoning in *SanDisk* that an Article III controversy arises when one party asserts its patent while the opposing party plans to continue its activity without obtaining a license.⁶³ Based on the parties’ statements and opposing positions, the court found a substantial controversy and affirmed the district court’s finding of jurisdiction.⁶⁴

Disagreement over royalties again served as the basis for declaratory judgment jurisdiction in a third 2007 decision, *Sony Electronics, Inc. v. Guardian Media Technologies, Ltd.*⁶⁵ *Sony*, *Matsushita*, *JVC*, and *Mitsubishi* sold technology that allowed users to block certain television content.⁶⁶ *Guardian* exchanged several letters with each of the companies, accusing them of infringing its patents, and in ***339** some instances had face-to-face meetings.⁶⁷ *Guardian* provided detailed claim charts comparing each limitation of several patent claims to the companies’ products.⁶⁸ *Guardian* also stated that the companies owed significant royalties.⁶⁹ After receiving demands for royalties and asserting their respective arguments that their products did not infringe any valid patent claims, the parties filed declaratory judgment actions for non-infringement, invalidity, and unenforceability in the U.S. District Court for the Southern District of California.⁷⁰

The district court consolidated the actions and granted *Guardian*’s motion to dismiss, holding that there was no actual controversy.⁷¹ The court also noted that *Guardian* never “expressly threatened to sue” and that its conduct did not amount to an “‘implicit threat of immediate litigation.’”⁷² The district court also stated that even if it had subject matter jurisdiction over the case, it would exercise its discretion not to hear the case because the declaratory judgment question was close and the lawsuits were an intimidation tactic to gain negotiation leverage.⁷³

The Federal Circuit acknowledged that district courts have “‘substantial discretion’” to decide whether to accept or dismiss a case but explained that district courts cannot be arbitrary or legally erroneous.⁷⁴ The Federal Circuit disagreed with the district court’s reasoning because (1) the facts did not present a “‘close case,’” and (2) even if the complaint had the effect of giving the appellants more negotiating leverage, there was no affirmative evidence to support an inference that the plaintiffs filed the declaratory judgment action to gain such leverage.⁷⁵ The Federal Circuit found that an actual controversy existed because *Guardian* asserted that it was owed royalties and the plaintiffs contended that they had the right to engage in activities without a license.⁷⁶ The disputes were definite and concrete because *Guardian* identified specific activities that it alleged infringed its patents and its opponents believed they could continue their activities without obtaining a license.⁷⁷ Accordingly, the Federal Circuit remanded the case to the district court for ***340** reconsideration.⁷⁸ On remand, the district court found jurisdiction, recognizing that, given the number of pending suits dependent upon the validity of *Guardian*’s patents, jurisdiction was appropriate to resolve the issue.⁷⁹

2. Correspondence Between the Patentee and Accused Infringer

Correspondence between parties may also suffice to establish an actual case or controversy for declaratory judgment jurisdiction, even absent licensing negotiations. In *Hewlett-Packard Co. v. Acceleron LLC*, the Federal Circuit found that a

letter to Hewlett-Packard (HP) proposing a discussion of Acceleron's patent established a substantial controversy despite the absence of an assertion of Acceleron's patent or an explicit threat of litigation.⁸⁰ HP proposed a standstill agreement, but Acceleron declined.⁸¹

The Federal Circuit found that Acceleron's letters created a controversy between the parties. The court noted that declaratory judgment jurisdiction "cannot be defeated simply by the stratagem of a correspondence that avoids the magic words such as 'litigation' or 'infringement.'"⁸² Otherwise, the court explained, any competent lawyer would avoid "the magic words," and a declaratory judgment lawsuit, when corresponding with potential infringers on behalf of patent owners.⁸³

The court also dismissed Acceleron's argument that it had not yet analyzed HP's product, stating that the test for declaratory judgment is objective and "conduct that can be reasonably inferred as demonstrating intent to enforce a patent can create declaratory judgment jurisdiction."⁸⁴ Given the totality of the circumstances--including Acceleron's status as a "licensing entity" that relied on patent enforcement to reap the benefits of its patents-- the court found that a substantial controversy existed between the parties.⁸⁵

Interestingly, the court commented that HP's act of filing the suit demonstrated its belief that Acceleron was asserting its patent rights against HP.⁸⁶ This runs counter to the idea that the existence of a case or controversy is an objective issue because it gives weight to HP's impression of Acceleron's actions. Moreover, this reasoning would support finding jurisdiction in every declaratory judgment action *341 because every plaintiff could argue that its decision to sue demonstrated the belief that the opposing party intended to assert its patent.

Correspondence threatening litigation can establish declaratory judgment jurisdiction even when the declaratory judgment plaintiff has set forth a state law defense. In *ABB Inc. v. Cooper Industries, LLC*, Cooper, the patent owner, wrote to ABB, stating that ABB's attempt to outsource the manufacturing of its allegedly infringing product "would be a material breach [of the license agreement between Cooper and ABB], and Cooper will act vigorously to protect its rights in that event."⁸⁷ Cooper also contacted Dow Chemicals, a third party manufacturer to whom ABB had outsourced its work, "to formally put Dow on notice that Cooper will vigorously defend its rights should Dow attempt to make products covered by one or more of Cooper's patents."⁸⁸

ABB then filed a declaratory judgment action seeking a declaration that it could outsource manufacturing under its license agreement with Cooper and that it did not infringe a valid or enforceable claim of Cooper's patents.⁸⁹ Cooper moved to dismiss for lack of subject matter jurisdiction because ABB raised only a state law defense by arguing that the license agreement authorized ABB to outsource its manufacturing.⁹⁰ The district court agreed and dismissed the case.⁹¹

On appeal, the Federal Circuit concluded that Cooper's letters established an immediate controversy sufficient to support declaratory judgment jurisdiction.⁹² The remaining portion of the court's opinion addressed whether a federal court had subject matter jurisdiction over a declaratory judgment claim when the plaintiff asserted a state law defense.⁹³ The Federal Circuit reversed the dismissal for lack of subject matter jurisdiction, emphasizing that the nature of the coercive action that prompts the declaratory judgment action, rather than the defense to the anticipated *342 litigation, determines declaratory judgment jurisdiction.⁹⁴ ABB was concerned that Cooper would sue for patent infringement, and it is the infringement suit, not ABB's defense, that courts consider for purposes of declaratory judgment jurisdiction.⁹⁵ The Federal Circuit explained that "Cooper could unquestionably bring its patent infringement claim in the federal courts, even if ultimate resolution of the case depended entirely on ABB's state law defense, because an infringement suit is a federal cause of action."⁹⁶

Correspondence between the declaratory judgment plaintiff and the patent holder will not always trigger declaratory judgment jurisdiction, however, particularly if the correspondence was initiated by the plaintiff to establish facts to support a declaratory judgment action. In *Innovative Therapies, Inc. v. Kinetic Concepts, Inc.*, Innovative employees telephoned Kinetic employees who lacked authority to make decisions about litigation tactics for Kinetic, the patent owner.⁹⁷ Nonetheless, the plaintiff cited comments from these employees as the foundation of its perceived threat of litigation.⁹⁸ The district court found that telephone calls made to the patentee's employees, who were neither informed of the purpose of the calls nor authorized to make decisions, did not suffice to establish a substantial controversy of sufficient immediacy and reality.⁹⁹

The Federal Circuit agreed, finding that statements made during informal phone calls characterized by "indirection" did not establish a substantial case or controversy to justify declaratory judgment jurisdiction.¹⁰⁰ The Federal Circuit was persuaded by the fact that Kinetic, although engaged in litigation with others, had not directed any affirmative acts toward Innovative.¹⁰¹

Furthermore, the district court emphasized that the existence of a controversy must be determined as of the filing date of the original complaint.¹⁰² After Innovative filed its declaratory judgment action, Kinetic sued Innovative in Texas for breach of confidentiality and misappropriation of trade secrets and in the Middle *343 District of North Carolina for infringement.¹⁰³ Innovative amended its declaratory judgment complaint to add this activity as proof of an actual controversy.¹⁰⁴ The district court explained that amending the complaint after the patent owner started litigating its patents against the plaintiff in another jurisdiction did not cure a lack of subject matter jurisdiction as of the date the complaint was filed.¹⁰⁵ The district court noted that to hold otherwise would lead declaratory judgment plaintiffs to file complaints as early as possible and attempt to create retroactive jurisdiction.¹⁰⁶ The Federal Circuit agreed, stressing that jurisdiction must exist at the outset of the lawsuit and cannot be established in an amended pleading based on subsequent events.¹⁰⁷

3. Industry Litigation and Public Statements

Although conduct directed toward the declaratory judgment plaintiff can evidence a substantial controversy, a patent owner's actions towards other companies in an industry can also evidence a substantial controversy. In *Micron Technology, Inc. v. MOSAID Technologies, Inc.*, MOSAID, the patent owner, sent warning letters to Micron and three other leading manufacturers in its industry, suggesting that they license its patents related to dynamic random access memory chips (DRAMs).¹⁰⁸ MOSAID began enforcing its patents in court against manufacturers other than Micron.¹⁰⁹ The cases settled, often after the defendants agreed to license the patents.¹¹⁰ After each settlement, MOSAID issued public statements reiterating its aggressive licensing strategy.¹¹¹

Micron then filed a complaint for a declaratory judgment of non-infringement of fourteen MOSAID patents in the Northern District of California.¹¹² The next day, MOSAID sued Micron in the Eastern District of Texas for infringing seven patents.¹¹³ The California court granted MOSAID's motion to dismiss, finding no jurisdiction under the reasonable apprehension of suit test because MOSAID had not made threats against Micron or its customers for four years and had not mentioned Micron's name in its public comments.¹¹⁴

*344 On appeal, the Federal Circuit found that the combination of MOSAID's history of enforcing its patents against the DRAM industry, its recent public statements confirming its "intent to continue an aggressive litigation strategy," and its next-day infringement suit against Micron in Texas combined to create a substantial controversy of sufficient immediacy and reality.¹¹⁵ The court also found that the DJA's objectives would be met by allowing the California court to hear the case, reasoning that the purpose of the Act is to "provide the allegedly infringing party relief from uncertainty and delay regarding its legal rights."¹¹⁶

In *Panavise Products, Inc. v. National Products, Inc.*, however, the patent owner's previous litigation against other companies did not establish a substantial controversy between the patent owner and Panavise.¹¹⁷

National Products, Inc. (NPI) initiated six infringement lawsuits between January 2005 and February 2007 on its patent for suction cup mounting devices.¹¹⁸ Panavise filed a complaint for a declaratory judgment of non-infringement one year later.¹¹⁹ Panavise maintained that NPI had created a substantial controversy of sufficient immediacy and reality because (1) NPI had likely observed Panavise's new product at a trade show, (2) Panavise had already manufactured, produced, publicly used, and distributed arguably infringing products, and (3) NPI had a history of enforcing its patent.¹²⁰

The Federal Circuit affirmed the district court's dismissal of the declaratory judgment complaint, observing that although Panavise had sold its Model 711 device for eleven years, NPI had never accused that product of infringement even though it was "substantially identical to the allegedly potentially infringing [Model 811] product."¹²¹ The court was careful not to imply that "the lack of direct pre-complaint communication between [the parties] by itself is sufficient to defeat subject matter jurisdiction."¹²² Nevertheless, Panavise did not submit any evidence to show that its Model 811 device was similar to the products that NPI had accused of *345 infringement in its prior cases.¹²³ The court concluded that NPI's history of routinely enforcing its patent rights was insufficient to create an actual controversy.¹²⁴

4. Covenants Not to Sue

Patent owners may protect themselves from facing declaratory judgment actions by granting covenants not to sue. In particular, broad language disclaiming all rights to enforce a patent against an ANDA applicant eliminates a substantial controversy between a patent owner and the applicant as to that patent. In *King Pharmaceuticals, Inc. v. Eon Labs, Inc.*, Elan,

the original patent holder, assigned its rights to the patents-in-suit to King Pharmaceuticals.¹²⁵ Although Elan attempted to extricate itself from the litigation between King and Eon, the ANDA applicant, the district court denied Elan's motion to dismiss itself from the case.¹²⁶

After the court granted summary judgment of invalidity of the patents-in-suit, Elan appealed, arguing that the district court did not have subject matter jurisdiction to enter a summary judgment against it because Elan had assigned all of its rights to King.¹²⁷ The Federal Circuit agreed, highlighting that Elan sold its interests in the patents, represented in its pleadings that it would waive its rights to the patents, and provided Eon "broad and unrestricted covenants not to sue . . . for infringement" of the patents-in-suit.¹²⁸ Therefore, no case or controversy existed between Elan and Eon. The court upheld the district court's judgment of patent invalidity entered against King.¹²⁹

A covenant not to sue also destroyed declaratory judgment jurisdiction in *Dow Jones & Co. v. Ablaise Ltd.*¹³⁰ In *Dow Jones*, Ablaise, the patent owner, offered Dow Jones a licensing agreement.¹³¹ But Dow Jones refused to enter into a license agreement and instead filed a declaratory judgment action seeking a declaration of invalidity of Ablaise's two patents--U.S. Patent Nos. 6,961,737 and *346 6,295,530.¹³² The patents claimed methods for creating individualized web pages.¹³³ After a Markman hearing, Ablaise offered Dow Jones a covenant not to sue on the '530 patent, but Ablaise refused to extend the covenant to include Dow Jones' parent company, News Corporation.¹³⁴ Ablaise then moved to dismiss the invalidity claim with respect to the '530 patent, arguing that its offer of a covenant not to sue stripped the court of subject matter jurisdiction.¹³⁵

The district court denied Ablaise's motion to dismiss and held the '530 and '737 patents invalid.¹³⁶ The Federal Circuit reversed the denial of Ablaise's motion to dismiss the invalidity claim as to the '530 patent, stating that Ablaise's offer of a covenant not to sue "extinguished any current or future controversy between the parties [with respect to the '530 patent], and divested the district court of subject matter jurisdiction."¹³⁷ The court explained that the covenant need not include the parent corporation, News Corporation, reasoning that a parent company is insulated from liability ascribed to its subsidiary.¹³⁸

A limited covenant not to sue, however, will not always shield a patent owner from declaratory judgment actions. In a case involving eyewear, Revolution sued Aspex for infringement, and Aspex counterclaimed for a declaratory judgment of non-infringement, invalidity, and unenforceability.¹³⁹ Soon thereafter, Aspex discontinued selling the accused eyewear.¹⁴⁰ After sparring in the district court, Revolution offered Aspex a covenant not to sue for infringement based on prior activities and moved to dismiss for lack of jurisdiction.¹⁴¹ The district court granted the motion.¹⁴²

On appeal, Aspex argued that an actual controversy continued because the covenant only applied to past acts of infringement, and Aspex intended to reintroduce its eyewear into the market.¹⁴³ The court cited *MedImmune* and *SanDisk* for the principle that "declaratory judgment jurisdiction is met when the patentee 'puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal *347 behavior or abandoning that which he claims a right to do.'"¹⁴⁴ Although a simple interest in marketing a patented product does not alone create a definite and concrete conflict, Aspex wanted to sell its existing inventory.¹⁴⁵ Revolution stated that it would return to court if Aspex reentered the market.¹⁴⁶ The Federal Circuit noted that (1) the parties were already in litigation initiated by Revolution, (2) Revolution filed its covenant not to sue after four years of litigation and on the eve of trial, and (3) the covenant was largely meaningless because Aspex had removed its product from the market while the case was pending and the covenant did not shield future sales of the same eyewear.¹⁴⁷ Accordingly, the court reversed the district court's dismissal of Aspex's counterclaims, concluding that by retaining the right to sue in the future, Revolution had "preserved this controversy at a level of 'sufficient immediacy and reality.'"¹⁴⁸

5. ANDA Submissions

Disputes between brand drug manufacturers and ANDA applicants often require analyzing whether declaratory judgment jurisdiction exists. In *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, Teva filed an ANDA and Novartis sued Teva on one of its five Orange Book-listed patents.¹⁴⁹ Teva then sought a declaratory judgment on Novartis' other Orange Book patents.¹⁵⁰ The district court found that Teva failed to establish a reasonable apprehension of imminent suit with respect to the four method patents and dismissed Teva's claims.¹⁵¹

On appeal, Novartis argued that there was not an actual controversy on the four method patents because it "has not filed suit nor threatened to sue Teva on [those] patents."¹⁵² The Federal Circuit reversed the district court's decision, relying heavily on the legislative history of the Hatch-Waxman Act.¹⁵³ In the legislative history, Congress stated:

*348 We fully expect that, in almost all situations where a generic applicant has challenged a patent [by

filing an ANDA with a paragraph IV certification] and not been sued for patent infringement, a claim by the generic applicant seeking declaratory judgment on the patent will give rise to a justiciable ‘case or controversy’ under the Constitution.¹⁵⁴

Congress noted that the only exceptions would be the brand company’s grant of a covenant not to sue the generic company or the brand company’s acknowledgement of non-infringement.¹⁵⁵ The legislative history specifically addressed the situation in which a brand company might, for tactical reasons, assert only one of several Orange Book patents and concluded that “generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug.”¹⁵⁶ The court concluded that a number of factors, including Novartis’ Orange Book listing, Teva’s ANDA filing, and Novartis’ lawsuit on at least one patent, combined to establish an actual controversy on all five patents.¹⁵⁷

Despite finding declaratory judgment jurisdiction in *Teva v. Novartis*, the existence of other Orange Book patents that are not asserted in a lawsuit does not automatically establish declaratory judgment jurisdiction. For example, if the first ANDA filer has stipulated to infringement and validity of one of the Orange Book patents, current law requires all ANDA filers to wait for the expiration of that patent before launching their products (unless the first filer’s marketing exclusivity expires earlier).¹⁵⁸ Under these facts, the direct cause of an ANDA filer’s injury is the stipulation of infringement and validity, not a substantial controversy with the patent holder.

This unusual fact pattern was seen in *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*¹⁵⁹ Janssen listed three Orange Book patents for its drug, RISPERDAL Oral Solution, which is used to treat schizophrenia, bipolar disorder, and irritability associated with autism.¹⁶⁰ U.S. Patent 4,804,663 was set to expire six years before Janssen’s other two listed patents, U.S. Patent 5,453,425 and U.S. *349 5,616,587.¹⁶¹ Teva, the first ANDA filer, filed Paragraph IV certifications challenging the ‘425 and ‘587 patents, but it filed a Paragraph III certification for the ‘663 patent, respecting that patent’s validity.¹⁶² Janssen did not sue Teva on the ‘425 and ‘587 patents.¹⁶³ Consequently, the FDA would be able to approve Teva’s drug upon the ‘663 patent’s expiration.¹⁶⁴ Teva’s 180-day exclusivity period could then be triggered by either its product launch or a final court judgment that both the ‘425 and ‘587 patents are invalid or not infringed, despite the fact that Teva could not launch its product until the ‘663 patent expired.¹⁶⁵

Apotex, the second ANDA filer, filed Paragraph IV certifications challenging all three patents.¹⁶⁶ Janssen sued Apotex for infringing the ‘663 patent but not the ‘425 or ‘587 patents.¹⁶⁷ Apotex counterclaimed for a declaratory judgment of non-infringement of the ‘425 and ‘587 patents.¹⁶⁸ Janssen moved to dismiss these counterclaims for lack of case or controversy.¹⁶⁹ Janssen subsequently gave Apotex a covenant not to sue on the ‘425 and ‘587 patents, and Apotex stipulated to infringement, validity, and enforceability of the ‘663 patent.¹⁷⁰ The district court granted Janssen’s motion to dismiss the counterclaims regarding the ‘425 and ‘587 patents.¹⁷¹

Apotex appealed, arguing that it was harmed because it could only trigger Teva’s exclusivity period before the ‘663 patent expired by obtaining a judgment of invalidity or non-infringement for both the ‘425 and ‘587 patents.¹⁷² Without such a judgment, Apotex’s approval would be delayed indefinitely if Teva did not trigger its 180-day exclusivity period by launching its product.¹⁷³

But the court noted that the harm Apotex suffered was due to the fact that it had stipulated to infringement, validity, and enforceability of the ‘663 patent.¹⁷⁴ *350 Even if Apotex successfully invalidated the ‘425 and ‘587 patents, it could not obtain FDA approval until the ‘663 patent expired.¹⁷⁵ Thus, Apotex was blocked from the market by a valid patent.¹⁷⁶

The only harm that Apotex faced was that it had to wait for Teva’s exclusivity period to end once the ‘663 patent expired, and the court explained that this harm could not establish declaratory judgment jurisdiction because Teva was entitled to its exclusivity period under the Hatch-Waxman Act.¹⁷⁷ Apotex’s market entry could be delayed if Teva did not launch its product and trigger the 180-day exclusivity period.¹⁷⁸ But the court reiterated that the controversy must be “definite and concrete” and “real and substantial” to find jurisdiction and stated that “a possible delay in the future of a first Paragraph IV ANDA filer in launching its generic product does not give rise to declaratory judgment jurisdiction.”¹⁷⁹ Accordingly, the Federal Circuit affirmed the district court’s dismissal of the case.¹⁸⁰

Recently, the Federal Circuit found jurisdiction where the first ANDA filer’s exclusivity period again blocked the declaratory judgment plaintiff’s access to the market. In *Teva Pharmaceuticals USA, Inc. v. Eisai Co., Ranbaxy* was the first filer for an ANDA seeking approval to make a generic version of Aricept (used to treat dementia), for which Eisai had five Orange

Book-listed patents: U.S. Patent Nos. 5,985,864, 6,140,321, 6,245,911, 6,372,760, and 4,895,841.¹⁸¹ Before the case arose, Eisai filed statutory disclaimers with the patent office regarding the '321 and '864 patents, effectively cancelling the patent claims.¹⁸² Ranbaxy filed a Paragraph III certification for the '841 patent.¹⁸³ Ranbaxy was therefore barred from marketing its generic drug until expiration of the '841 patent in November 2010.¹⁸⁴

Teva subsequently submitted two ANDA applications for different forms of generic Aricept and filed Paragraph IV certifications for all five listed patents.¹⁸⁵ *351 Eisai then sued Teva for infringement of the '841 patent.¹⁸⁶ Eisai eventually obtained a preliminary injunction against Teva with respect to the '841 patent and Teva stipulated that the preliminary injunction would remain in effect until the '841 patent expired in November 2010.¹⁸⁷

Teva brought a declaratory judgment action against Eisai for the four remaining listed patents in May 2008.¹⁸⁸ Eisai granted Teva a covenant not to sue regarding the '911 and '760 patents and then argued that its covenant and statutory disclaimer of the other listed patents defeated subject matter jurisdiction.¹⁸⁹ However, the Orange Book still listed the disclaimed patents.¹⁹⁰ Teva argued that its injury was traceable to the listed patents because, regardless of Eisai's disclaimer of the '321 and '864 patents, the FDA could not approve its ANDA while the four patents were listed in the Orange Book.¹⁹¹

The court relied on Caraco and Janssen to analyze Teva's argument. The court explained that "[w]hen an Orange Book listing creates an 'independent barrier' to entering the marketplace that cannot be overcome without a court judgment . . . the company manufacturing the generic drug has been deprived of an economic opportunity to compete."¹⁹² The court explained that the injury in Janssen was due to the subsequent filer's stipulation of patent validity, not the brand company's decision to list patents in the Orange Book.¹⁹³ Unlike the plaintiff in Janssen, Teva *352 did not stipulate to validity, enforceability, or infringement of any listed patent.¹⁹⁴ The court clarified that, unlike the stipulation of validity in Janssen, Teva's stipulation to extend the preliminary injunction until the '841 patent's expiration was not a "final judgment."¹⁹⁵

B. Immediacy and Concrete Steps

In addition to being substantial, a controversy worthy of declaratory judgment jurisdiction must also be sufficiently real or immediate. This portion of the standard has not received as much attention as the substantial controversy prong.¹⁹⁶ The question of immediacy often turns on whether the accused product is ready for commercialization and whether any requisite regulatory approval is sufficiently imminent. Interestingly, the absence of post-MedImmune decisions by the Federal Circuit applying the concrete steps part of the test suggests that the concrete steps prong might collapse into the sufficient immediacy or reality requirement.¹⁹⁷

Even in the presence of a substantial controversy between the parties, lack of immediacy will preclude the court from exercising declaratory judgment jurisdiction. In *Benitec Australia, Ltd. v. Nucleonics, Inc.*, Benitec sued Nucleonics for infringing a patent related to RNA-based disease therapy in 2004.¹⁹⁸ Nucleonics initially moved to dismiss the case because it would not be ready to file a New Drug Application (NDA) "until at least 2010-2012, if ever."¹⁹⁹ Yet, after discovering that Benitec's inventor misappropriated the idea for the invention from others, Nucleonics added declaratory judgment counterclaims for invalidity and unenforceability.²⁰⁰ Benitec moved to dismiss the case because "it had no presently viable infringement claim against Nucleonics."²⁰¹ The district court granted the motion to dismiss.²⁰²

On appeal, the Federal Circuit concluded that Nucleonics' clinical work to develop a product for human application did not "present a case or controversy of *353 sufficient immediacy and reality" because it did not expect to submit its NDA for at least another three years.²⁰³ Nucleonics alternatively argued that it was developing a product for animal husbandry and veterinary applications using the same RNA technology.²⁰⁴ The Federal Circuit rejected that argument because Nucleonics presented insufficient evidence of its work, pointing only to "discussions with an unnamed potential customer and execution of an undescribed confidentiality agreement."²⁰⁵ The court also found that Benitec had never challenged use of the RNA-based technology for animal use.²⁰⁶

In *Cat Tech LLC v. TubeMaster, Inc.*, the issue turned on the status of product development rather than regulatory approval.²⁰⁷ Cat Tech's patent concerned loading devices that placed catalyst particles into chemical reactors.²⁰⁸ TubeMaster developed four different configurations of its loading devices and generated detailed manufacturing drawings for each configuration.²⁰⁹ Cat Tech sued TubeMaster for infringement of its design.²¹⁰ TubeMaster counterclaimed for a declaratory judgment that none of its configurations infringed the patent and that the patent was invalid and unenforceable.²¹¹ TubeMaster's designs were customized based on the dimensions of each customer's reactor, so it could not manufacture its

loading devices until it received a customer order with the appropriate dimensions.²¹² But the district court nevertheless found a live controversy because TubeMaster had taken sufficient concrete steps and was prepared to produce the devices as soon as it received a customer order.²¹³

The Federal Circuit affirmed the district court's exercise of declaratory judgment jurisdiction.²¹⁴ The court explained that the concrete steps prong remained an important element and that in the absence of "significant, concrete steps" to infringe, a dispute could not be immediate or real.²¹⁵ The court found that the "[c]onstitutionally mandated immediacy requirements have been satisfied because once the threat of liability to Cat Tech has been lifted, it appears likely that TubeMaster *354 can expeditiously solicit and fill orders."²¹⁶ The court explained that "the reality requirement is often related to the extent to which the technology in question is 'substantially fixed' as opposed to 'fluid and indeterminate' [when] declaratory relief is sought."²¹⁷ The court found that TubeMaster's technology was substantially fixed because TubeMaster could make and sell its products without significant alteration once the cloud of infringement liability is lifted.²¹⁸

IV. Constitutional Minimum: Standing, Ripeness, and Mootness

In two of its post-MedImmune cases, the Federal Circuit focused its analysis on the standing, ripeness, and mootness requirements for establishing an Article III case or controversy.²¹⁹ In instances where the court has applied this analysis, the MedImmune standard appears secondary to the constitutional analysis.

A. Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.

Forest held an approved NDA for its drug, LEXAPRO.²²⁰ Forest listed two patents in the Orange Book for LEXAPRO, U.S. Patents Re. 34,712 and 6,916,941.²²¹ Ivax and Caraco were the first and second ANDA applicants, respectively.²²² Forest sued Ivax for infringing the '712 patent and obtained a judgment that Ivax infringed the '712 patent.²²³ Forest did not sue on the '941 patent.²²⁴

Caraco was prohibited from obtaining FDA approval and entering the market until after Ivax's 180-day exclusivity period expired.²²⁵ However, Ivax could not trigger its exclusivity period until after the '712 patent expired because it had been adjudged to infringe the '712 patent.²²⁶ Caraco had the ability to trigger the exclusivity *355 period, but Caraco could only do so by obtaining a judgment that both the '712 and '941 patents were invalid or not infringed.²²⁷

As it had done with Ivax, Forest sued Caraco for infringing the '712 patent but not the '941 patent.²²⁸ Caraco then filed a complaint for a declaratory judgment of non-infringement of the '941 patent.²²⁹ Forest granted Caraco a covenant not to sue under the '941 patent, but refused to concede that the '941 patent was invalid or not infringed.²³⁰ Forest then moved to dismiss the declaratory judgment complaint for lack of a case or controversy regarding the '941 patent.²³¹ The district court agreed, stating that the covenant not to sue eliminated the threat of a lawsuit.²³²

On appeal, the Federal Circuit quoted the MedImmune test.²³³ However, without applying the MedImmune test, the court then turned to "the Supreme Court's three-part framework for determining whether an action presents a justiciable Article III controversy."²³⁴ Citing three different Supreme Court cases, the Federal Circuit looked to whether (1) Caraco had standing, (2) the issues were ripe for review, and (3) the case had been rendered moot at any stage of the litigation.²³⁵

The Federal Circuit explained that for Caraco to have standing, it must establish that (1) it had suffered an injury-in-fact, (2) the injury was traceable to Forest, and (3) the injury would be redressed by a favorable judgment.²³⁶ The Federal Circuit concluded that (1) Caraco's claim that it was being restrained from the free exploitation of non-infringing goods was "exactly the type of injury-in-fact that is sufficient to establish Article III standing," (2) Forest's act of listing its patents in the Orange Book caused the delay in Caraco's FDA approval, satisfying the traceability requirement for Article III standing, and (3) a declaratory judgment that the '941 patent is not infringed would redress Caraco's injury-in-fact.²³⁷ Thus, Caraco had standing.

On the issue of ripeness, the court concluded that additional factual development would not advance the district court's ability to decide the case because Caraco already had "a complete generic drug product that ha[d] been submitted to the *356 FDA for approval."²³⁸ On the third factor, mootness, the Federal Circuit acknowledged that Forest's covenant not to sue eliminated any reasonable apprehension of suit and that usually a covenant not to sue would allow the recipient to enter the marketplace.²³⁹ But in the ANDA context, "a generic manufacturer cannot enter the market without FDA approval."²⁴⁰ The

covenant, therefore, did not moot the substantial controversy created by the dispute as to the validity and infringement of the '941 patent.²⁴¹ The Federal Circuit accordingly reversed the district court's grant of Forest's motion to dismiss.²⁴²

B. Prasco, LLC v. Medicis Pharm. Corp.

Medicis sold a benzoyl peroxide cleansing product, TRIAZ, that it marked with four patent numbers.²⁴³ Shortly before it started selling its competing generic benzoyl peroxide cleansing product, Prasco filed a complaint for declaratory judgment that its product would not infringe Medicis' four patents.²⁴⁴ Seven months earlier, Medicis had sued Prasco for infringing an unrelated patent with a different cleanser.²⁴⁵ A prior case between the same parties carries minimal weight, however, if it involves different products and an unrelated patent.²⁴⁶ After Medicis moved to dismiss the initial complaint, Prasco started selling its product and requested a covenant not to sue from Medicis under the four patents.²⁴⁷ Medicis did not sign the covenant, and Prasco amended its complaint to include these new facts.²⁴⁸ The district court granted Medicis' motion to dismiss for lack of declaratory judgment jurisdiction.²⁴⁹

On appeal, the Federal Circuit began its analysis by quoting MedImmune's substantial controversy of sufficient immediacy and reality standard.²⁵⁰ But the court again turned to the three-part test of standing, ripeness, and mootness to determine whether a substantial controversy existed to satisfy MedImmune.²⁵¹ The court explained that "[w]hile [the MedImmune] standard can be analyzed directly, *357 the Supreme Court has also developed various more specific but overlapping doctrines rooted in the same Article III inquiry, which must be met for a controversy to be justiciable, including standing, ripeness and a lack of mootness."²⁵² The court noted that these three doctrines "can be a helpful guide" because they represent "the absolute constitutional minimum for a justiciable controversy."²⁵³ More importantly, the court indicated that it had to find an Article III case or controversy before it could reach the issue of declaratory judgment jurisdiction.²⁵⁴

The court focused the rest of its analysis on standing. Medicis had not accused Prasco of infringement or asserted any rights against Prasco's product.²⁵⁵ Consequently, Prasco faced a "high barrier to proving that [it] face[d] an imminent risk of injury."²⁵⁶ The court doubted Prasco's argument that it had "paralyzing uncertainty" about whether Medicis would sue for patent infringement because Prasco admitted that any uncertainty had not been paralyzing, and it launched its product while the lawsuit was pending.²⁵⁷ In addition, "the bedrock rule that a case or controversy must be based on a real and immediate injury or threat of future injury that is caused by the defendants [is] an objective standard that cannot be met by a purely subjective or speculative fear of future harm."²⁵⁸ Instead, the basis for injury in most justiciable controversies is a "restraint on the free exploitation of non-infringing goods."²⁵⁹ Medicis had not tried to bar Prasco from the market; in fact, Prasco was selling its product.²⁶⁰

The Federal Circuit also discounted the three facts that Prasco cited as the basis for its fear of suit. First, Medicis' patent marking "provide[d] little, if any, evidence that it [would] ever enforce its patents."²⁶¹ In any event, Medicis' decision to mark its products before gaining any knowledge of Prasco's product was irrelevant to whether Medicis believed that Prasco's product infringes.²⁶² Second, although a prior suit concerning different products and an unrelated patent is entitled to some weight, it does not create a reasonable assumption that Medicis will take action *358 against Prasco's new product.²⁶³ Finally, Medicis' failure to sign a covenant not to sue, although relevant, is not dispositive.²⁶⁴

In short, Prasco had not suffered an actual injury traceable to Medicis, and Medicis had not asserted any rights against Prasco. Although the court understood "Prasco's desire to have a definitive answer on whether its product infringes [Medicis'] patents," it explained that deciding the case on the merits would be an impermissible advisory opinion.²⁶⁵

V. Discretionary Dismissal

Even if a substantial controversy of sufficient immediacy exists between parties, district courts have broad discretion to decline to exercise declaratory judgment jurisdiction.²⁶⁶ A district court's discretion is not unbounded, however. The Federal Circuit will not uphold a discretionary dismissal of a case that is arbitrary or erroneous.²⁶⁷

The Federal Circuit reviews a district court's decision to decline jurisdiction for abuse of discretion.²⁶⁸ The Eisai court examined the limits on district court discretion. In Eisai, the district court stated that even if it found that the two-part test was met, it would exercise its discretion to decline to hear the dispute.²⁶⁹ Teva argued that the Hatch-Waxman Act and 35 U.S.C. § 271(e)(5) require a court to hear a dispute once the two-part declaratory judgment standard has been met.²⁷⁰ The Federal

Circuit rejected this argument, finding that the language of §§ 271(e)(5) and 2201 confirmed that the district courts retain the discretion that the DJA grants them.²⁷¹

The Federal Circuit acknowledged that the district court may exercise its discretion to decline jurisdiction even where subject matter jurisdiction exists. For example, *359 the Federal Circuit has upheld discretionary decisions declining jurisdiction “when the declaratory judgment action was [1] duplicative of other proceedings, [2] the party instituted an action solely to enhance its bargaining power in negotiations, or [3] when reexamination proceedings were pending.”²⁷² However, the court clarified that “the district court must typically consider the usefulness of the declaratory judgment remedy, the fitness of the case for resolution, and the purposes of the Declaratory Judgment Act.”²⁷³

In *Eisai*, the Federal Circuit concluded that the district court abused its discretion because of at least two errors. First, the district court should not have considered whether it had subject matter jurisdiction in then determining whether to exercise its discretion to hear the case.²⁷⁴ The existence of jurisdiction is not probative of the discretionary factors under the DJA.²⁷⁵ Second, the facts did not present any of the “typical factors that might warrant the exercise of discretion to decline jurisdiction.”²⁷⁶ Furthermore, there was an actual controversy between the parties, and a declaratory judgment would provide appropriate relief.²⁷⁷

VI. Implications

As is clear from the Federal Circuit’s application of *MedImmune*, declaratory judgment jurisdiction is more fact-dependent than ever. However, comparing similar fact patterns among the post-*MedImmune* decisions allows for several conclusions.

First, it is clear that courts require an affirmative act by the patent owner, such as a demand for royalties or an invitation to discuss the owner’s patents, to establish declaratory judgment jurisdiction.²⁷⁸ Notably, these acts need not be directed towards the declaratory judgment plaintiff; public statements and litigation threats to others in the industry can suffice, especially when such threats demonstrate aggressive litigation tactics.²⁷⁹

Second, a covenant not to sue may block a plaintiff from establishing declaratory judgment jurisdiction in some instances.²⁸⁰ The covenant’s terms dictate *360 whether a substantial controversy is found. For example, the covenant in *King* was broad enough to eliminate the existence of a case or controversy, while the covenant in *Revolutionary Eyewear* did not eliminate the potential for a lawsuit against future sales.²⁸¹ ANDA litigants may be particularly affected because brand companies may gain additional platforms to initiate lawsuits by obtaining and listing additional patents. Meanwhile, a party seeking to avoid declaratory judgment by granting a covenant not to sue should clearly set forth its intentions and should not retain any rights that may later create a case or controversy.

Third, patent owners must be prepared to litigate when they initiate licensing negotiations.²⁸² The Federal Circuit has found declaratory judgment jurisdiction in four of the five post-*MedImmune* declaratory judgment appeals it has heard that involved license negotiations. This suggests that a potential licensee can often establish an actual controversy once a patent owner demands a license for the patent. In fact, licensees can fulfill their royalty obligations under a licensing agreement while seeking a declaration of invalidity or non-infringement. Therefore, to compensate for increased litigation risks, patent holders may decide to seek higher royalty rates or lump sum payments in their license agreements. Patent holders might also include trigger clauses that terminate the agreement or increase the royalty rates if the licensee files a lawsuit challenging the patent.

Footnotes

^{a1} Kelsey I. Nix is a partner in the Intellectual Property department at Willkie Farr & Gallagher LLP in New York (knix@willkie.com).

^{d1} Laurie Stempler is an associate in the Intellectual Property department at Willkie Farr & Gallagher LLP in New York (lstempler@willkie.com).

1 MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007).

2 An applicant seeking approval for a generic drug submits an ANDA to the U.S. Food and Drug Administration (FDA), which details how its product, the subject of the ANDA, is equivalent to the brand drug. In particular, the ANDA filer must demonstrate that its product has the same active ingredient, route of administration, dosage form, strength, and approved use as the brand drug. Shashank Upadhye, *Generic Pharmaceutical Patent and FDA Law* §§ 7:3-7:4 (2010). The ANDA must also include a certification to particular patents that cover the drug. *Id.* § 10:3. The ANDA filer may certify that the brand drug owner has not listed any patent (Paragraph I), that the listed patent has expired (Paragraph II), that approval should be delayed until the listed patent expires (Paragraph III), or that the patent is invalid or will not be infringed (Paragraph IV). *Id.* Filing a Paragraph IV certification constitutes a technical act of infringement. 35 U.S.C. § 271(e)(2) (2006).

3 12 James Wm. Moore et al., *Moore's Federal Practice* P 57App.03 (3d ed. 2011).

4 See *id.* P 57.83 (“The party accused of infringement had few means to vindicate its reputation because, if the suit was found to be baseless, the sole result would be the dismissal of the action.”).

5 *Id.*

6 *Id.* P 57App.02[1].

7 *Id.*

8 *Id.* P 57App.02[2] (quoting Section 1 of the UDJA).

9 Moore et al., *supra* note 3, P 57App.02[2] (quoting Section 6 of the UDJA).

10 *Id.* (quoting Section 7 of the UDJA).

11 *Id.* P 57.App.02[1].

12 See *Nashville, C. & St. L. Ry. v. Wallace*, 288 U.S. 249, 263-64 (1933) (explaining that the procedure used to establish a case or controversy can vary and emphasizing that the Constitution does not limit how a party invokes jurisdiction and that the only requirements are that “the case retains the essentials of an adversary proceeding, involving a real, not a hypothetical, controversy”).

13 Moore et al., *supra* note 3, P 57.03[2].

14 28 U.S.C. § 2201 (2006).

15 Moore et al., *supra* note 3, P 57.83[1]. The Federal Circuit’s post-MedImmune decisions have involved plaintiffs who are not patent holders and seek declarations of invalidity or non-infringement with respect to the patents-in-suit. However, patent owners may also seek declaratory judgments of infringement to clarify their rights and are subject to the same standard as the plaintiffs discussed in this article. See, e.g., *Abbott Diabetes Care, Inc. v. Dexcom, Inc.*, No. 05-590, 2006 WL 2375035, at *3 (D. Del. Aug. 16, 2006) (finding patent holder Abbott’s complaint did not present an actual controversy when filed); *Interdigital Tech. Corp. v. OKI Am., Inc.*, 845 F. Supp. 276, 286 (E.D. Pa. 1994) (finding that patent holder ITC presented a “justiciable controversy”).

16 See Moore et al., *supra* note 3, P 57.83 (“[C]ompetitors facing or threatened with an infringement claim may seek a declaratory

judgment that the patent is invalid; the only alternative would be for competitors to incur liability for patent infringement or terminate the enterprise.”).

17 See *Technical Tape Corp. v. Minn. Mining & Mfg. Co.*, 200 F.2d 876, 878 (2d Cir. 1952) (“Once the patentee has made some claim, directly or indirectly, so that notice is given that it asserts that there is or will be an infringement, a justiciable controversy exists, entitling the alleged infringer to seek declaratory relief.”).

18 E.g., *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1339 (Fed. Cir. 2007) (emphasis added). This article focuses on patent cases. However, declaratory judgment actions also arise in the context of copyright and trademark infringement as well. Courts apply the reasonable apprehension standard to determine whether an actual controversy exists in copyright infringement cases: one party must make or sell, or prepare to make or sell, a product that would infringe the owner’s copyright despite the copyright owner’s actions and, consequentially, possess a reasonable apprehension of suit. See *Moore et al.*, supra note 3, P57.22[8][e]. In trademark cases, the plaintiff also must have a reasonable apprehension of suit, and the plaintiff’s conduct must create an adversarial conflict with the trademark owner. *Windsurfing Int’l Inc. v. AMF Inc.*, 828 F.2d 755, 757 (Fed. Cir. 1987); *Moore et al.*, supra note 3, P 57.22[8][d]. But both copyright and trademark cases have applied *MedImmune* and noted its impact on the standard for determining declaratory judgment. See, e.g., *Surefoot LC v. Sure Foot Corp.*, 531 F.3d 1236, 1241-43 (10th Cir. 2008) (applying *MedImmune* in a trademark infringement suit and noting that the Federal Circuit’s declaratory judgment standard in patent contexts applies to copyright and trademark suits); *Segone, Inc. v. Fox Broad. Co.*, No. 3:07-CV-342, 2007 WL 2965064, at *2 (E.D. Va. Oct. 9, 2007) (applying *MedImmune* to determine jurisdiction in a copyright infringement suit).

19 See generally Lisa A. Dolak, *Declaratory Judgment Jurisdiction in Patent Cases: Restoring the Balance Between the Patentee and the Accused Infringer*, 38 B.C. L. Rev. 903, 906-07 (1997) (exploring the Federal Circuit’s interpretation of the actual controversy requirement and noting a change in its application of the two-part standard).

20 *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 136 (2007); see also *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271, 1287-88 (Fed. Cir. 2007) (indicating that the district court’s discretion is not unbounded--the district court’s decision to decline to exercise jurisdiction may not be arbitrary or legally erroneous).

21 *MedImmune*, 549 U.S. at 127-29.

22 *Id.* at 121.

23 *Id.*

24 *Id.* at 121-22.

25 *Id.* at 122.

26 *Id.*

27 *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 963 (Fed. Cir. 2005), rev’d, 549 U.S. 118 (2007).

28 *Id.* at 964.

29 *Id.* at 963.

30 *MedImmune*, 549 U.S. at 127-29.

31 Id. at 131.

32 Id. at 127 (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)) (internal quotation marks omitted).

33 See *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008); see *infra* Part IV.A (discussing the role of the reasonable apprehension of suit in the Caraco decision).

34 *Altvater v. Freeman*, 319 U.S. 359 (1943).

35 *MedImmune*, 549 U.S. at 130-31.

36 Id. at 132.

37 Id. at 134-35.

38 Id.

39 See *infra* Part III.A.1.

40 See *infra* Part III.A.2.

41 See *infra* Part III.A.3.

42 See *infra* Part III.A.4.

43 See *infra* Part III.A.5.

44 *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 880 (Fed. Cir. 2008); see *infra* Part III.B (discussing the immediacy and concrete steps requirements for establishing declaratory judgment jurisdiction).

45 The Federal Circuit reviews a district court's denial of subject matter jurisdiction *de novo*. *Teva Pharms. USA, Inc. v. Eisai Co., Ltd.*, 620 F.3d 1341, 1346 (Fed. Cir. 2010). Likewise, whether an actual controversy exists is a question of law that is also reviewed *de novo*. Id.

46 *SanDisk Corp. v. STMicroelectronics*, 480 F.3d 1372, 1375-76 (Fed. Cir. 2007).

47 Id. at 1375.

48 Id.

49 Id.

50 Id.

51 Id. at 1376.

52 SanDisk, 480 F.3d at 1376.

53 Id. at 1381.

54 Id. at 1382.

55 Id. at 1383 (quoting Arrowhead Indus. Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 735 (Fed. Cir. 1988)).

56 Id. at 1378 (quoting MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 133 (2007)).

57 Adenta GmbH v. OrthoArm Inc., 501 F.3d 1364 (Fed. Cir. 2007).

58 Id. at 1370.

59 Id. at 1366.

60 Id.

61 Id. (internal quotation marks omitted).

62 Id. at 1366-67.

63 Adenta, 501 F.3d at 1370.

64 Id.

65 497 F.3d 1271, 1281-82, 1286-87 (Fed. Cir. 2007).

66 Id. at 1274, 1276, 1279.

67 Id. at 1275-81.

68 Id. at 1275, 1277.

69 Id. at 1276, 1278, 1280.

70 Id. at 1276, 1279, 1281.

71 Sony, 497 F.3d at 1281.

72 Id. (quoting Sony Elecs., Inc. v. Guardian Media Techs., Ltd., No. 05-CV-1777-B, slip. op. at 16 (S.D. Cal. Mar. 16, 2006)).

73 Id.

74 Id. at 1287-88 (quoting Wilton v. Seven Falls Co., 515 U.S. 277, 286 (1995)).

75 Id. at 1288-89 (quoting Sony Elecs., Inc. v. Guardian Media Techs., Ltd., No. 05-CV-1777-B, slip. op. (S.D. Cal. Mar. 16, 2006)).

76 Id. at 1286.

77 Sony, 497 F.3d at 1285-87. See *infra* Part III.B for further discussion of the concrete steps portion of the test.

78 Id. at 1289.

79 Sony Elecs., Inc. v. Guardian Media Techs., Ltd., No. 05-CV-1777-B, 2007 WL 3333113, at *2 (S.D. Cal. Nov. 6, 2007) (“Now that Guardian has sued several other manufacturers for patent infringement, the need for a judicial resolution of the validity of its’ [sic] patents is apparent.”).

80 Hewlett-Packard Co. v. Acceleron LLC, 587 F.3d 1358, 1363-64 (Fed. Cir. 2009).

81 Id. at 1360-61.

82 Id. at 1362.

83 Id.

84 Id. at 1363.

85 Id. at 1364.

86 Hewlett-Packard, 587 F.3d at 1363.

87 ABB Inc. v. Cooper Indus., LLC., No. 2010-1227, 2011 WL 553603, at *1 (Fed. Cir. Feb. 17, 2011) (internal citations and quotation marks omitted).

88 Id.

89 Id.

90 Id. at *2.

91 Id.

92 Id. at *3. The same type of analysis applies in the context of indirect infringement. In *Arris Group, Inc. v. British Telecommunications PLC*, the Federal Circuit reversed the district court and found an actual controversy when an equipment supplier sought a declaratory judgment of no indirect infringement and invalidity. No. 2010-1292, slip op. at 2 (Fed. Cir. May 19, 2011). Arris supplied cable telephony components for Cable One's network. Id. British Telecommunications PLC (BT) alleged that Cable One's network infringed its patents. Id. BT sent letters and infringement contentions to both Cable One and Arris, and BT met with both Cable One and Arris to discuss licensing. Id., at 3-6. In finding jurisdiction, the Federal Circuit concluded that "BT's infringement accusations against Cable One carried the implied assertion that Arris was committing contributory infringement, and BT repeatedly communicated this implicit accusation directly to Arris during the course of a protracted negotiation process." Id. at 22-23.

93 *ABB*, 2011 WL 553603, at *3-6.

94 Id. at *3 ("[F]or declaratory judgment suits, the character of the action is judged based on the declaratory judgment defendant's hypothetical complaint.").

95 Id. at *4.

96 Id.

97 *Innovative Therapies, Inc. v. Kinetic Concepts, Inc.*, 599 F.3d 1377, 1380-81 (Fed. Cir. 2010).

98 Id.

99 *Innovative Therapies, Inc. v. Kinetic Concepts, Inc.*, No. 07-589-SLR/LPS, 2008 WL 4809104, at *2 (D. Del. Nov. 5, 2008), *aff'd*, 599 F.3d 1377 (Fed. Cir. 2010).

100 *Innovative*, 599 F.3d at 1381.

101 Id. at 1382 ("[W]hile prior litigation is a circumstance to be considered in assessing the totality of circumstances, the fact that KCI had filed infringement suits against other parties for other products does not, in the absence of any act directed toward ITI, meet the minimum standard discussed in *MedImmune*.").

102 Id. at 1384.

103 Id. at 1382-83.

104 Id. at 1383.

105 Id.

106 Innovative, 599 F.3d at 1384.

107 Id.

108 Micron Tech., Inc. v. MOSAID Techs., Inc., 518 F.3d 897, 899 (Fed. Cir. 2008).

109 Id.

110 Id.

111 Id.

112 Id. at 900.

113 Id.

114 Micron, 518 F.3d at 900.

115 Id. at 901-02.

116 Id. at 902 (quoting Goodyear Tire & Rubber Co. v. Releasomers, Inc., 824 F.2d 953, 956 (Fed. Cir. 1987)).

117 Panavise Prods., Inc. v. Nat'l Prods., Inc., 306 Fed. App'x 570, 573-74 (Fed. Cir. 2009) (nonprecedential).

118 Id. at 571.

119 Id.

120 Id.

121 Id. at 573 (internal quotation marks omitted).

122 Id.

123 Panavise, 306 Fed. App'x at 573.

124 Id. at 573-74. Indeed, in a more recent decision, a different panel of the court stated that “the fact that [the patent owner] had filed infringement suits against other parties for other products does not, in the absence of any act directed toward [the declaratory judgment plaintiff], meet the minimum standard discussed in *MedImmune*.” *Innovative Therapies, Inc. v. Kinetic Concepts, Inc.*, 599 F.3d 1377, 1382 (Fed. Cir. 2010) (emphasis added).

125 *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1282 (Fed. Cir. 2010).

126 Id. at 1281.

127 Id. at 1282.

128 Id.; see also *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1363 (Fed. Cir. 2008) (holding that a covenant not to sue covered generic drug manufacturer along with its suppliers, affiliates, and customers).

129 *King Pharm.*, 616 F.3d at 1270.

130 606 F.3d 1338, 1349 (Fed. Cir. 2010).

131 Id. at 1344.

132 Id.

133 Id. at 1340.

134 Id. at 1344.

135 Id.

136 *Dow Jones*, 606 F.3d at 1344.

137 Id. at 1348.

138 Id. at 1349. The court affirmed the district court’s grant of summary judgment with respect to the 737 patent. Id. at 1352-53.

139 *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 556 F.3d 1294, 1295 (Fed. Cir. 2009).

140 Id.

141 Id. at 1296.

142 Id.

143 Id.

144 Id. at 1298 (quoting *SanDisk Corp. v. STMicroelectronics*, 480 F.3d 1372, 1381 (Fed. Cir. 2007)).

145 *Revolution Eyewear*, 556 F.3d at 1298-99.

146 Id. at 1299.

147 Id.

148 Id. at 1300; see *infra* Part III.B (discussing immediacy as a requirement for establishing declaratory judgment jurisdiction).

149 *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1334-35 (Fed. Cir. 2007). The FDA publishes the Orange Book. Under the Hatch-Waxman Act, an entity seeking FDA approval to make and sell its drug must list in the Orange Book all patents that may cover its drug. Generic manufacturers seeking to rely on the original manufacturer's safety and efficacy studies must file a certification regarding each of the patents listed for that drug. 21 U.S.C. § 355(b) (2006).

150 *Teva Pharm.*, 482 F.3d at 1335.

151 Id.

152 Id. at 1340.

153 Id. at 1343-45; 21 U.S.C. § 355 (2006). The Hatch-Waxman Act established a shortcut for generic drug manufacturers. Under the Hatch-Waxman Act, generic manufacturers submit certifications to listed patents. See *supra* note 2. Through this scheme, the generic manufacturer can rely on the original manufacturer's safety and efficacy data to obtain approval of its ANDA. The Hatch-Waxman Act also defines a litigation framework to guide the brand and generic companies through patent litigation that originates when the generic company files its ANDA. See generally 21 U.S.C. § 355 (2006); 35 U.S.C. § 271(e)(2) (2006); see *Dey, L.P. v. Sepracor, Inc.*, 595 F. Supp. 2d 355, 356 (D. Del. 2009).

154 *Teva Pharms.*, 482 F.3d at 1343 (alteration in original) (quoting 149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy)).

155 Id. (quoting 149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy)).

156 Id. at 1344 (quoting 149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy)) (emphasis added).

157 Id. at 1341-45.

158 *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1283 (Fed. Cir. 2008).

159 540 F.3d 1353, 1360 (Fed. Cir. 2008).

160 Id. at 1357; Risperdal, <http://www.risperdal.com> (last visited March 14, 2011).

161 Janssen, 540 F.3d at 1357-58.

162 Id. at 1358; see also *supra* note 2 (discussing the differences between Paragraph III and Paragraph IV certifications under the Hatch-Waxman Act).

163 Janssen, 540 F.3d at 1358.

164 Id.

165 Id. at 1360.

166 Id. at 1358.

167 Id.

168 Id.

169 Janssen, 540 F.3d at 1358.

170 Id. at 1358, 1360.

171 Id. at 1359.

172 Id. at 1359-60.

173 Id. at 1362. Apotex also argued that the covenant not to sue did not cover its affiliates, suppliers, and customers. The court tersely reached a contrary conclusion based on the express language of the covenant. Id. at 1363.

174 Id. at 1361.

175 Janssen, 540 F.3d at 1361.

176 Id. at 1360-61. In both *Caraco* and *Janssen*, the second ANDA filer was blocked from the market by the first filer's 180-day exclusivity period. In both cases, the second filer could accelerate and trigger that exclusivity period only by successfully challenging the patents. The court's focus on Apotex's stipulation concerning one of the three patents does not appear to fully reconcile the results in the two cases.

177 Id. at 1361.

178 Id. at 1362.

179 Id. at 1363.

180 Id. at 1363-64.

181 Teva Pharms. USA, Inc. v. Eisai Co., 620 F.3d 1341, 1343-44 (Fed. Cir. 2010).

182 Id. at 1345.

183 Id. at 1344.

184 Id.

185 Id.

186 Id. at 1345.

187 Eisai, 620 F.3d at 1345. The court explained that Teva's stipulation regarding the preliminary injunction did not divest the court of declaratory judgment jurisdiction because the parties did not enter the stipulation prior to Teva's appeal of the dismissal of its action. Moreover, the stipulation was "only relevant, if at all," until the 841 patent's expiration. Even after the 841 has expired, Teva is barred from launching its generic product by the patents that are the subject of its declaratory judgment action. Id. at 1348 n.4.

188 Id. at 1345.

189 Id.

190 Id.

191 Id.

192 Eisai, 620 F.3d at 1347.

193 Id. at 1347-48. The Eisai decision could prove important for subsequent ANDA filers (e.g., generic manufacturers who are not first-to-file). Apotex recently relied on the Eisai decision to argue for declaratory judgment jurisdiction in the Eastern District of Michigan. Complaint for Declaratory Judgment and Demand for Jury Trial at 13-14, Apotex Inc. v. Forest Labs., Inc., No. 11-CV-10129 (E.D. Mich. Jan. 10, 2011). Apotex cites the Medicare Modernization Act (MMA), 21 U.S.C. § 355(j)(5)(c)(i), for the proposition that it has a statutory right to file a declaratory judgment action against the owner of an Orange Book listed patent who failed to sue within 45 days after receiving Apotex's Notice Letter. Id. at 3, 6. Citing Eisai, Apotex alleges that it is sustaining an "FDA-approval-blocking injury" due to the first filer's 180-day exclusivity period. Id. at 13-14 (internal quotation marks deleted) (quoting Eisai, 620 F.3d at 1343). Apotex argues that a judgment of non-infringement would trigger the first filer's exclusivity period, which would redress Apotex's injury. Id. at 21. Apotex is in the early stages of pleading. Its outcome may inform how broadly courts are willing to read Eisai.

194 Eisai, 620 F.3d at 1347-48.

195 Id. at 1348. In reversing the district court, the Federal Circuit also concluded that the district court had abused its discretion in declining to adjudicate the dispute. Id. at 1349; see also *infra* Part V (discussing district courts' discretion in exercising declaratory judgment jurisdiction).

196 The Federal Circuit discussed immediacy and concrete steps in *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 556 F.3d 1294 (Fed. Cir. 2009). See *supra* Part III.A.4 (discussing covenants not to sue).

197 See *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 874, 880 (Fed. Cir. 2008) (mentioning concrete steps under a “real or immediate” test); *SanDisk Corp. v. STMicroelectronics*, 480 F.3d 1372, 1379 (Fed. Cir. 2007) (mentioning concrete steps as a component of a formerly two-part test for declaratory judgment jurisdiction).

198 *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1342 (Fed. Cir. 2007).

199 Id.

200 Id.

201 Id. at 1343.

202 Id.

203 Id. at 1346.

204 *Benitec*, 495 F.3d at 1348.

205 Id. at 1348-49.

206 Id. at 1349.

207 *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 881-82 (Fed. Cir. 2008).

208 Id. at 874.

209 Id. at 877.

210 Id. at 877-78. *TubeMaster* had not sold any of the designs.

211 Id.

212 Id. at 881-82.

213 Cat Tech, 528 F.3d at 878.

214 Id. at 874.

215 Id. at 880.

216 Id. at 882.

217 Id. (quoting *Sierra Applied Scis., Inc., v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1379 (Fed. Cir. 2004)).

218 Id. at 882-83.

219 The Federal Circuit decided the first of these cases focusing on standing, ripeness and mootness after hearing only six post-MedImmune cases. Judge Gajarsa authored both opinions. *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1333 (Fed. Cir. 2008); *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1281 (Fed. Cir. 2008). Interestingly, Judge Gajarsa also wrote the earlier opinion in *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330 (Fed. Cir. 2007), which did not apply the standing, ripeness, and mootness analysis.

220 *Caraco*, 527 F.3d at 1286.

221 Id.

222 Id. at 1286, 1288.

223 Id. at 1286.

224 Id.

225 See id. at 1287.

226 *Caraco*, 527 F.3d at 1287.

227 Id.

228 Id. at 1288.

229 Id.

230 Id. at 1289.

231 Id.

232 Caraco, 527 F.3d at 1289.

233 Id. at 1290.

234 Id. at 1291.

235 Id. (citing Lujan v. Defenders of Wildlife, 504 U.S. 555 (1992); United States Parole Comm'n v. Geraghty, 445 U.S. 388, 397 (1980); Abbott Labs. v. Gardner, 387 U.S. 136, 140 (1967)).

236 Id.

237 Id. at 1292-93.

238 Caraco, 527 F.3d at 1295.

239 Id. at 1296.

240 Id.

241 Id. at 1297.

242 Id.

243 Prasco, LLC. v. Medicis Pharm. Corp., 537 F.3d 1329, 1334 (Fed. Cir. 2008).

244 Id.

245 Id.

246 Id. at 1341.

247 Id. at 1344.

248 Id.

249 Prasco, 537 F.3d at 1340.

250 Id. at 1334.

251 Id. at 1336.

252 Id. (emphasis added).

253 Id. (emphasis added).

254 Id. at 1335 (citations omitted) (“[The Declaratory Judgment Act] provides a remedy available only if the court has jurisdiction from some other source. Such jurisdiction is limited by Article III of the Constitution”).

255 *Prasco*, 537 F.3d at 1340.

256 Id.

257 Id. at 1338.

258 Id. at 1339.

259 Id. (quoting *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008)).

260 Id. at 1338-39.

261 *Prasco*, 537 F.3d at 1340.

262 Id. at 1340-41.

263 Id. at 1341.

264 Id.

265 Id. at 1341-42.

266 *MedImmune v. Genentech, Inc.*, 549 U.S. 118, 136 (2007) (interpreting the DJA).

267 See *supra* Part III.A.1 (discussing *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271 (Fed. Cir. 2007)). The Federal Circuit applies an abuse of discretion standard when reviewing the district court’s exercise of discretion. *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271, 1288 (Fed. Cir. 2007).

268 *Teva Pharms. USA, Inc. v. Eisai Co., Ltd.*, 620 F.3d 1341, 1346 (Fed. Cir. 2010).

269 Id. at 1348.

270 Id.

271 Id. (noting that 35 U.S.C. § 271(e)(5) “clarifies the maximum extent of a court’s jurisdiction” by providing that district courts “shall” have subject matter jurisdiction to the extent consistent with the Constitution. However, § 271(e)(5) does not override a Court’s discretion under the DJA, which provides that federal courts “may declare the rights and other legal relations of an interested party seeking such declarations” (quoting 28 U.S.C. § 2201(a) (2006)) (internal quotation marks omitted).

272 Id.

273 Id. at 1349.

274 Eisai, 620 F.3d at 1349.

275 Id.

276 Id.

277 Id.

278 See supra Part III.A (discussing the substantial controversy requirement for establishing declaratory judgment jurisdiction).

279 See supra Part III.A.3.a (discussing *Micron Tech., Inc. v. MOSAID Techs., Inc.*, 518 F.3d 897 (Fed. Cir. 2008)).

280 See supra Part III.A.4 (discussing the impact of covenants not to sue on the substantial controversy requirement for establishing declaratory judgment jurisdiction).

281 See supra Part III.A.4 (discussing both *King* and *Revolutionary Eyewear*).

282 See supra Part III.A.1 (discussing the impact of a patentee’s offers and demands to license on the substantial controversy requirement for establishing declaratory judgment jurisdiction).